

# Shelf life of reprocessible medical devices: a scope review on the application and limitations of microbiological testing.

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## 1. Background

Studies argue that maintaining the sterility of surgical instruments depends on the integrity of the packaging, storage conditions, and handling. However, several institutions choose to use an expiration date based on microbiological sterility testing.

What are the existing evidences on the use of microbiological testing to determine the shelf life of sterilized RMD in CSSD?

## 2. Methods

- Scope review → JBI methodology
- Databases: PubMed, Cinahl, Scopus, Embase, Cochrane, the Virtual Health Library, Google Scholar and Proquest
- Selection and analysis of studies: independently by two researchers
- Report: Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Scoping Reviews.

## 3. Results and discussion

### Records

2.256 found 52.7% quasi-experimental

96 eligible 28.9% did not specify the sterilization method

36 included

Most analyzed packaging: paper (41.5%) and fabric (35.8%)

Shelf life: two days (shortest), 11 years (longest) and 180 day (most prevalent)

### Microbiological Sterility Testing

54.2% positive → Nine (47.3%) reported the possibility of accidental contamination

45.7% negative → Three studies deemed the samples sterile even with the presence of growth, justifying the contamination as accidental.

Only seven (19.4%) studies presented **complete information** on the sterility test.

Failures in the processing and development of infections

- Aseptic technique
- Laminar flow
- Help tool
- Seeding medium
- Incubation time and temperature

Staphylococcus sp,  
Bacillus spp,  
Streptococcus sp,  
Aspergillus spp and  
Fusarium spp

**Only one study performed incubation in the appropriate seeding medium, time and temperature.**

## 4. Conclusions

**Microbiological sterility testing is not recommended to determine the sterilization shelf life of RMD**

- Heterogeneous studies, with methodological and theoretical gaps in the execution of the test.
- The test is not sufficient to identify and analyze the flaws in the CSSD processing.
- Event-related sterility: savings of resources and infection prevention



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